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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,830	01/30/2002	Yizhong Gu	PB0169	3442
7590 03/31/2004				
Stephen G. Ryan Amersham Biosciences 800 Centennial Avenue Piscataway, NJ 08855			EXAMINER SWOPE, SHERIDAN	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,830	GU, Y. ET AL	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-49 is/are pending in the application.
- 4a) Of the above claim(s) 13-31, 34-38, and 40-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-12, 32, 33, 39, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>0204</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's Amendment and Request for Continuing Examination, received February 24, 2004, in response to the Final Rejection of this case mailed July 29, 2003, is acknowledged. It is acknowledged that applicants have cancelled Claim 2 and amended Claims 1, 48, and 49. Claims 1 and 3-49 are pending. Claims 13-31, 34-38, and 40-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 1, 2-12, 32, 33, 39, 48, and 49 are hereby reconsidered.

Claim Rejections - 35 USC § 101

Rejection of Claims 1, 3-12, 32, 33, 39, 48, and 49 under 35 U.S.C. 101 because the claimed invention lacks patentable utility, as described in the prior actions, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

—When newly discovered compounds [that] belong to a class of compounds, the members of which have become well recognized as useful for a particular purpose because of a particular property, the only reasonable conclusion is that the new compounds, also possessing that property, are similarly useful. *In re Folkers* 344 F.2d 970,974 (C.C.P.A. 1965) at 975.

The claimed subject matter comprises nucleic acid sequence encoding a transmembrane protein with an N-terminal signal peptide. These proteins also contain an LCCL domain, a discoidin domain, and a truncated CUB domain. Kobuke et al, 2001, who teach that the gene is up-regulated after vascular injury, independently identified these features.

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Koshikawa et al, 2002 teach that expression of the gene is significantly up-regulated in a significant fraction of lung cancers *in vivo* with high frequency in metastatic lesions. These finding are in agreement with Applicant's belief that the gene and encoded polypeptides are useful in developing therapeutics as well as diagnostics for neurological and developmental disorders and tumors.

Because the claim nucleic acid sequences can be used to produce useful proteins, the claimed invention is useful. –

These arguments are not found to be persuasive for the following reasons. It is acknowledged that if a polynucleotide encodes polypeptide that has a high level of similarity with a protein known to have a specific function, a person of ordinary skill in the art would conclude said polypeptide has the same specific function. However, at the time of filing, the polypeptide of the instant application was not known to be highly homologous to any protein known to have a specific function. The presence of certain domains in the instant polypeptide gives some insight into what the function of said polypeptide might be, but does not establish what the function is. It is acknowledged that Koshikawa et al teach that the instant protein can be used as a marker for metastatic lung cancer (Fig 3). However, said specific utility was not asserted in the instant application. The specification states that the instant polypeptide is important for neurological and developmental disorders as well as diseases involving cell-cell adhesion and are a cause of human diseases involving the adrenal, liver, bone marrow, brain, liver, heart, kidney, lung, placenta, skeletal muscle, colon, or prostate (pg 119, parag 1). The specification goes on to state that the polynucleotides and antibodies to polypeptides of the instant invention can be used as probes to assess the levels in adrenal, liver, bone marrow, brain,

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liver, heart, kidney, lung, placenta, skeletal muscle, colon, or prostate in order to diagnose neurological and developmental disorders as well as diseases involving cell-cell adhesion (pg 129, line 29- pg 130, line 7). Such a laundry list of diseases and disorders the recited polypeptide might be involved in is not an assertion of what the function of said polypeptide is. It is acknowledged that any cDNA can be used to produce the encoded polypeptide. However, a skilled artisan would not be motivated to make the polypeptide encoded by recited the polynucleotides for a patentable utility, as said polypeptide has no substantial and specific use.

Claim Rejections - 35 USC § 112-First Paragraph

Rejection of Claims 1, 3-12, 32, 33, 39, 48, and 49 under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a convincing asserted utility or a well established utility and, therefore, one skilled in the art clearly would not know how to use the claimed invention is also maintained.

The further rejection of Claims 1, 3-12, 32, 33, 39, 48, and 49 under 35 U.S.C. 112, first paragraph, for lack of enablement is also maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

—Applicants have amended claims 1, 48, and 49 to delete the recitation of sequences with a percent identity to either SEQ ID NO: 2, SEQ ID NO: 1113, SEQ ID NO: 3, and SEQ ID NO: 1114. The claims now only recite sequences with a percent identity to SEQ ID NO: 1115 or SEQ ID NO: 1116. SEQ ID NO: 1115 contains the novel splice junction sequence of LCP2, while SEQ ID NO: 1116 is the encoded polypeptide. Both are relatively short sequence that are part of SEQ ID NO: 1113 and SEQ ID NO: 1114, respectively. Thus, the descriptions that the Examiner identified as resulting in the impermissible broadening the scope of the claims, due to

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the extremely large number of polynucleotides broadly encompassed by the claims, has now been eliminated from claims 1, 48 and 49. Therefore, Applicants respectfully submit that the basis for the rejection has been eliminated. –

It is acknowledged that Applicants have limited the scope of Claims 1, 48, and 49 to only recite the polynucleotides of SEQ ID NO: 1113, encoding SEQ ID NO: 1114, having at least 90%, 95% or 99% identity with SEQ ID NO: 1115, or encoding a polypeptide having at least 90%, 95% or 99% identity with SEQ ID NO: 1116. However, Applicant's arguments are not found to be persuasive. The effect of replacement of any amino acid residue in a protein can be unpredictable. For example, Wishart et al, 1995 teach that a single mutation of a Gly residue to a Cys residue (G¹²⁰C) converts a phosphotyrosine binding-domain into a dual-specificity phosphatase (Fig 4). While, as taught by Witkowski et al, 1999, a single mutation of a Cys residue for a Gln residue (C¹⁶¹Q) converts a β -ketoacyl synthase to a malonyl decarboxylase (Fig 3). Without a recitation of a specific function for the polypeptides encoded by the polynucleotides of Claims 1, 48, and 49, a person of ordinary skill in the art would not know how to use said polynucleotides. Therefore, rejection of Claims 1, 3-12, 32, 33, 39, 48, and 49 under 35 U.S.C. 112, first paragraph, for lack of enablement is maintained.

Rejection of Claims 1, 3-12, 32, 33, 39, 48, and 49 under 35 U.S.C. 112, first paragraph, for lack of written description, is also maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. –Claims 1, 48, and 49 have been amended to more clearly set forth the claimed invention. [As described above- Examiner's comment.] In view of said amendments

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one of ordinary skill in the art can clearly determine that Applicants were in possession of the invention at the time of filing. –

These arguments are not found to be persuasive for the following reasons. The specification does not contain any disclosure of the function of all polynucleotides having at least 90%, 95%, or 99% identity with SEQ ID NO: 1115 or encoding a polypeptide with at least 90%, 95%, or 99% identity with SEQ ID NO: 1116. The genus of polynucleotides that comprise these above polynucleotide is a variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims, including partial DNA sequences. The specification does not disclose the function of any species of the claimed genus and, thus, does not put one of skill in the art in possession of the attributes and features of any species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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